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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/372,380	08/11/1999	ROMAN M. CHICZ	08191/008003	1336
7590	09/04/2002			
JANIS K FRASER FISH & RICHARDSON PC 225 FRANKLIN STREET BOSTON, MA 021102804			EXAMINER ZHOU, SHUBO	
		ART UNIT 1631	PAPER NUMBER 16	
		DATE MAILED: 09/04/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/372,380	CHIEZ ET AL.
	Examiner Shubo "Joe" Zhou	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 May 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14, 17-21 and 43-92 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-14, 17-21, and 43-92 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

It is noted that an inadvertent error was made in a previous Office action mailed 7/29/02. Applicant is notified that the Office action is hereby vacated, and the following restriction requirement constitutes what is currently being applied to the instant application.

Response to RCE and Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/02 has been entered.

The Examiner acknowledges receipt of the Amendment/Reply accompanying the RCE request filed on 5/9/02. The Amendment has been entered.

Currently, claims 1-14, 17-21, and 43-92 are pending.

Restriction/Election Requirement

Upon further consideration of the restriction requirement mailed 12/12/00, it is noted that the claims in Group I encompass multiple inventions that are patentably distinct as set forth below. Furthermore, applicants' amendment to the claims filed 5/9/02 requires further search for the continued examination of the application. For example, a critical limitation added to many claims in the amendment is that the

polypeptide ligands are "produced in the cell", and bind to receptors "present in the cell". Thus, the following additional restriction of Group I was deemed necessary.

Multiple telephone called were made to Applicants' representative, Mr. Jack Brennan in the week of 7/22/02 through 7/26/02 for an election on the telephone. However, Mr. Brennan informed the Examiner that applicants could not be reached and requested the restriction/election requirement be mailed to applicants.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I.1. Claims 1-9, 43-62 and 84-88, drawn to a singular ligand profile, would be classified in Class 702, subclass 19 if the invention were patentable.
- I.2. Claims 10-13, 63-67 and 89, drawn to methods of generating a ligand profile involving one type of receptor, classified in Class 435, subclass 7.1.
- I.3. Claims 14, 68-72, and 90, drawn to methods of generating a ligand profile involving one type of receptor, classified in Class 435, subclass 7.1.
- I.4. Claims 17-20, 73-78, and 91, drawn to methods of comparing cell samples using ligand profiles classified in Class 435, subclass 7.1.
- I.5. Claims 21, 79-83, and 92, drawn to a set of ligand profiles, would be classified in Class 702, subclass 19 if the invention were patentable.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I.1 and I.2); Groups (I.3 and I.5) and Group I.4 are directed to separate and distinct inventions. Groups (I.1 and I.2) are directed to a singular ligand profile and methods of generating the same; Groups (I.3 and I.5) are directed to a set of ligand profiles and method of generating the same; and Group I.4 is directed to comparing cell samples by generating and using ligand profiles. The

methods of generating a singular profile and a set of profiles as claimed are distinct both physically and functionally, require different process steps, reagents and parameters, and produce different products. The products as claimed, i.e. the singular profile and set of profiles are distinct both physically and functionally also, and require different process steps, reagents and parameters to produce. Consequently, these inventions have acquired a separate status in the art as a separate subject for inventive effect and are usually published separately. The search for each of the above inventions is not co-extensive particularly with regard to the literature search.

The inventions of Groups I.1 and I.2 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the ligand profile of Group I.1 can be produced by the process of the invention of Group I.2, which is essentially an *in vivo* assays involving ligands produced in the cell and receptor in the cell. Or alternatively, the ligand profile can be produced by *in vitro* ligands and receptor binding and separating assays, which is a clearly distinct process of making such profile.

The inventions of Groups I.3 and I.5 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the set of ligand profiles of Group I.5 can be produced by the process of the invention of Group I.3, which is essentially an *in vivo* assays involving ligands produced in the cell and receptor in the cell. Or alternatively, the ligand profile can be produced by *in vitro* ligands and receptor

binding and separating assays, which is a clearly distinct process of making such profile.

Because these inventions are independent/distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

A fully responsive communication will comprise a proper election of a group, and sequences, as well as compliance with the sequence rules (or microfiche guidelines) as set forth above. Examination cannot proceed without a complete response.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.



Patent Examiner

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

